UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY, et al.

Plaintiffs

v.

Civil Action No. 2:21-cv-03500-MAK

TAKEDA PHARMACEUTICALS U.S.A., INC., et al.

Defendants.

PLAINTIFFS' PRETRIAL MEMORANDUM

Pursuant to the Court's April 14, 2023 Scheduling Order (ECF No. 904), Local Rule of Civil Procedure 16.1, and § VI.A of the Court's Policies and Procedures, Plaintiffs¹ respectfully submit the following Pretrial Memorandum in the above captioned action.

I. <u>NATURE OF THE ACTION AND JURISDICTION</u>

On August 5, 2021, Value Drug Company initiated this action under the private action provision of the Clayton Act (15 U.S.C. § 15(a)) for Defendants' violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, seeking overcharge damages resulting from Defendants' unlawful conspiracy to order the market and reduce output for 0.6 mg colchicine tablets and Takeda's monopolization. ECF No. 1. On April 14, 2023, Value Drug Company amended its complaint to join several additional Plaintiffs. *See* ECF No. 905.

¹ The Plaintiffs are: AmerisourceBergen Corporation; AmerisourceBergen Drug Corporation; Bellco Corporation; H.D. Smith, LLC; J.M. Blanco, Inc.; Valley Wholesale Drug Co., LLC; Burlington Drug Company; Cardinal Health, Inc.; Cardinal Health 110 LLC; Cardinal Health P.R. 120, Inc.; Dakota Drug, Inc.; J M Smith Corporation d/b/a Smith Drug Company; Louisiana Wholesale Drug Company, Inc.; McKesson Corporation; MLI Rx LLC; Morris & Dickson Co., L.L.C.; North Carolina Mutual Wholesale Drug Company; Prescription Supply, Inc.; RDC Liquidating Trust by and through its trustee, Advisory Trust Group LLC; and Value Drug Company.

² The Defendants are Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"); Watson Laboratories, Inc. ("Watson"); Teva Pharmaceutical Industries Ltd., Teva Pharmaceutical USA, Inc. (both "Teva"); and Amneal Pharmaceuticals LLC ("Amneal"). Par Pharmaceutical, Inc. ("Par") was dismissed on September 20, 2022 following its bankruptcy. ECF No. 521.

The Court has jurisdiction over the Plaintiffs' claims under 28 U.S.C. §§ 1331, 1337(a), and 15 U.S.C. § 15. Venue is appropriate under § 12 of the Clayton Act (15 U.S.C. § 22) and 28 U.S.C. § 1391(b) and (c).

II. STATEMENT OF FACTS

This case is about Takeda's inability in 2015 to accept the impending end of its lucrative exclusivity over Colcrys (colchicine 0.6mg tablets) and the resumption of generic competition. Takeda was about to lose its patent litigation against Par, Watson and Amneal, and was facing an impending flood of price-lowering competition. To avoid this, Takeda engineered a scheme to extend its monopoly over colchicine tablets past the period legally permitted. Takeda conspired to create an illicit joint venture with Par to divide the spoils of Takeda's monopoly and delay Par's price competition for up to six years. Takeda also secured the necessary participation in the conspiracy of Watson and Amneal, by agreeing to establish for them, after a long period of Takeda-Par exclusivity, an additional 135-day shared exclusivity period free from competition from any further generic entrants and a cash payment to Amneal of \$3.65 million. The effect of this scheme was to order the market and avoid the price competition that would have otherwise occurred. Given how demonstrably weak Takeda's patent infringement allegations were, this illicit joint venture had no redeeming competitive virtues. By participating in the conspiracy, each Defendant violated \$ 1 of the Sherman Act. Takeda also violated \$ 2 of the Sherman Act (monopolization).

Colchicine is a unpatentable gout treatment that has been used effectively dating back to antiquity, and was sold by dozens of drugmakers for pennies per tablet before the FDA's Unapproved Drug Initiative ("UDI") in 2006. Under the UDI, Takeda's predecessor, URL Pharma, submitted an application, performed certain studies, and thereby became the only approved seller of unpatentable colchicine, protected until July of 2016 with regulatory exclusivity called "orphan

drug exclusivity." After acquiring URL, Takeda took the price of colchicine from under \$0.10/tablet before the UDI, to over \$6/tablet.

When Takeda acquired Colcrys from URL, it also acquired patents purportedly covering the drug. But colchicine is a naturally occurring substance that is derived from a plant and has been used effectively as a gout treatment for thousands of years. Thus, the acquired patents covered only narrow methods of using colchicine, not the drug itself. It was apparent from the time of the acquisition that these patents could not stand up to challenge. Takeda's competitors agreed. By January 2011, Par's CEO bluntly concluded that "I don't see the protection," and instructed his team to rapidly pursue a generic.

Par filed its Abbreviated New Drug Application ("ANDA") in 2011, with a Paragraph IV certification to the FDA that Takeda's patents were either invalid, unenforceable, or would not be infringed. Amneal and Watson then filed ANDAs, each with the same certification. Takeda sued each of Par, Amneal, and Watson for patent infringement. These cases were all assigned to Judge Sue L. Robinson, and set to be jointly tried on December 9, 2015. Before the Colcrys patent trial, Judge Robinson issued an opinion in a different case about the same patents, ruling that Takeda was unlikely to prove that drugmaker Hikma infringed Takeda's colchicine patents by selling Mitigare, 0.6 mg colchicine *capsules* (as opposed to colchicine *tablets*). On May 16, 2015, the Federal Circuit affirmed Judge Robinson's Mitigare ruling. While Takeda would try to emphasize the minor distinctions between Mitigare and the Par, Amneal, and Watson generic colchicine products, any reasonable observer would conclude that Takeda was going to lose its patent trial, and thus its monopoly, and face a flood of generic competition which would bring prices back down to pennies per pill.

Desperate to avoid this outcome, Takeda conspired with Par, Amneal, and Watson to order their market entry and prevent the entry of generic Colcrys until years in the future, thereby reducing output and maintaining prices at supracompetitive levels. Their mutual promises comprising the conspiracy were contained in three interrelated written agreements that: (i) terminated the Par, Amneal, and Watson Colcrys patent infringement suits before Judge Robinson; (ii) established an illicit joint venture between Par and Takeda to divide between themselves the fruits of Takeda's unlawfully extended monopoly for years; (iii) secured Amneal and Watson's agreement through various inducements (explained below); and (iv) established an enforcement regime (that initially succeeded but ultimately failed) to keep non-conspirators off the market.

Under the terms of the Takeda-Par joint venture, Par abandoned its efforts to launch a Par generic form of Colcrys in 2016, and instead partnered with Takeda to step in to the shoes of an existing distributor, non-party Prasco, to distribute Takeda's brand Colcrys tablets – manufactured and supplied by Takeda – in authorized generic, or "AG" trade dress. Though their interests had once been antagonistic (as competitors), under the joint venture, Par was to revert most of the profits back to Takeda—aligning Takeda's and Par's interests in high pricing. As part of this joint venture, Takeda told Par that no other generic, including Watson or Amneal, would compete with it for several years.

Par was motivated to conspire. First, Par was the "first to file" ANDA filer for Colcrys, which earned it a 180-day FDA regulatory exclusivity during which the FDA could approve no other ANDA for Colcrys. But the value of this 180-day exclusivity was undermined on January 12, 2015 when Takeda launched AG Colcrys (through non-party Prasco). As Par's primary forecaster, live witness Carla Calabro, explained at the time, "This is not good! Our FTF value just disappeared." The conspiracy restored the "FTF value" to Par because Par would "step into the shoes of Prasco," whose AG license Takeda agreed to terminate on Par's behalf. Thus, instead of competing with Prasco, the conspiracy ensured Par would simply replace Prasco and have authorized generic Colcrys sales all to itself. Second, the conspiracy artificially extended Par's

exclusivity for 837 days (over 2 years) well beyond the 180 days permitted by the FDA. In later litigation, Par admitted that its participation in the conspiracy was predicated on Takeda's commitment to "police the market" by ensuring "a single generic market" for years when it was only ever eligible for 180 days of exclusivity.

Watson and Amneal were potential spoilers to the Takeda-Par joint venture because they were proceeding to an easy patent win. A win by either company would result in a forfeiture of Par's 180-day exclusivity under FDA regulations if Par failed to launch within 75 days of such win. Watson and Amneal thus knew that when they won, their entry would be no later than 180 days after Par's entry, and potentially as soon as 76 days after victory, and in settlement discussions, repeatedly demanded entry 180 days after Par's entry.

Takeda therefore needed to bring Watson and Amneal into the fold, and secured Par's agreement to share the terms of their joint venture. In doing so, Takeda revealed the conspiracy's objective to restrict Par's output altogether for two years and to then provide Par with Takeda's authorized generic product to sell starting in July of 2018 and extending for several years. To agree not to spoil the conspiracy and enter in January of 2019 (180 days after Par's starting to sell Takeda's AG), Watson demanded on behalf of itself and Amneal, and Takeda agreed to, a 135-day period, starting on October 15, 2020, during which Watson and Amneal would be the only additional generics permitted to enter, so that any other generic Colcrys ANDA filers could enter only after the 135th day that Watson and Amneal were on the market. This 135-day period of "shared semi-exclusivity" was woven from whole cloth – it is found nowhere in FDA regulations governing the intended timing of generic entry.

The shared semi-exclusivity period was valuable to Watson and Amneal because it would limit competition to just 3 generics in comparison to what Amneal and Watson's lawyers say was the "ever-present risk" of additional generic colchicine tablet competitors — essentially a return

to the 20-competitor market before URL got approval for its Colcrys tablets. Amneal was an intended beneficiary of the shared semi-exclusivity period and also extracted a \$3.65 million cash payment to agree to cede all generic tablet sales to Par for 837 days, until its October 15, 2020 entry date. By agreeing to launch on October 15, 2020, Watson and Amneal provided their horizontal competitor, Par, with 837 days of generic market exclusivity from its July 1, 2018 AG launch date, even though Par was only eligible for 180 days of exclusivity, a period which would have expired in January 2019.

As a result of the conspiracy and Takeda's willful maintenance of monopoly power, Plaintiffs were overcharged starting September 15, 2017, which is when Amneal and Watson (the latter acquired by Teva in August 2016) would have otherwise entered the market. That but-for world entry date is clear: the generics would have won at trial by July 2016; any marketing exclusivity preventing first-filer Par from launching would have expired by then; the generics would have received a favorable mandate from the Federal Circuit by July 2017; Par would have forfeited its 180-day exclusivity by September 15, 2017; and both Amneal and Teva would have received final FDA approval to launch, and would be prepared to do so, by that date.

III. RELIEF SOUGHT

Pursuant to § 4 of the Clayton Act, 15 U.S.C. § 15(a), Plaintiffs seek damages measured as the amount they were overcharged by Defendants, plus costs and attorney's fees. Trebling is mandatory under the Clayton Act, and is effectuated by the Court in molding any damages verdict in Plaintiffs' favor; the jury is not advised of the mandatory trebling.

IV. PLAINTIFFS' WITNESS LIST AND SUBSTANCE OF TESTIMONY

1. Donald Allen (expert)

Mr. Allen has 38 years of experience in pharmaceutical operations and supply chain management and currently offers consultations as President of Allen Performance Solutions. Mr. Allen will testify about the expert opinions he has formed in this case about the ability and timing of Amneal

and Watson/Teva to have commercially manufactured and launched their generic Colcrys products absent the challenged conduct and following a generic victory in the Colcrys patent litigation.

2. Glen Belvis (expert)

Mr. Belvis is an experienced patent attorney and expert witness on patent litigation issues. He will testify about the history of the ANDA litigation between Takeda and the Generics, and offer an opinion on how a reasonably experienced patent litigator would have evaluated the Generics' likelihood of success in the ANDA litigation.

3. Mary Bourke (fact witness identified with Takeda) Live

Ms. Bourke is a partner at Womble Bond Dickinson, LLP, in Wilmington, Delaware. She represented Takeda in the Colcrys patent litigation. Her testimony will focus on settlement negotiations, and the at-issue agreements and related conspiracy.

4. J. Mark Bover (fact witness identified with named plaintiff) Live

Mr. Bover is the Vice President of Operations at Value Drug based in Duncansville, PA. He will testify about Value Drug's business as a pharmaceutical wholesaler, its purchasing of Colcrys and generic Colcrys, the purchase prices of Colcrys and generic Colcrys, and how Value Drug overpaid due to Defendants' conduct.

5. Lawrence Brown (fact witness identified with Par) By Video

Lawrence Brown was the Par in-house intellectual property lawyer who negotiated the Takeda-Par Colcrys settlement. He will testify about those negotiations and the settlement, and Par's nonprivileged contemporaneous statements about the weakness of Takeda's intellectual property.

6. Carla Calabro (fact witness identified with Par) Live

Ms. Calabro is a current employee of Par Pharmaceuticals Inc. and in 2015 was Par's "Director, Sales & Marketing Analysis." Ms. Calabro will testify about her pricing, launch timing and competitive assumptions concerning generic Colcrys, and how and why they changed over time.

7. Paul Campanelli (fact witness identified with Par) Live

Mr. Campanelli is the former CEO of Par Pharmaceutical, Inc. and will testify about Par's negotiations with Takeda, the Takeda-Par settlement, Par's expectations for exclusivity, the impact to Par of incremental generic competition, litigation around Mylan's surprise entry, and Par's nonprivileged contemporaneous statements about the weakness of Takeda's intellectual property.

8. Ken Cappel (fact witness identified with Amneal) Live

Mr. Cappel was Amneal's Vice President of Global Intellectual Property. Mr. Cappel supervised Amneal's attorneys working on the Colcrys patent litigation and was responsible for Amneal's settlement negotiations with Takeda. His testimony will focus on the Colcrys patent litigation Amneal's nonprivileged contemporaneous statements about the weakness of Takeda's intellectual property, settlement negotiations, at-issue agreements and the related conspiracy.

9. Domenico Ciarico (fact witness identified with Par) Live

Mr. Ciarico was Par's Executive Vice President and Chief Commercial Officer, Sterile and Generics. He will testify about the nature of the Takeda-Par joint venture, the benefits to Par and Takeda therefrom, litigation around Mylan's entry, and the risk to Par and Takeda from incremental generic competition.

10. Joyce DelGaudio (fact witness identified with Watson/Teva) Live

Ms. DelGaudio is Senior Director of Regulatory Affairs for Generic Business Unit at Teva Pharmaceuticals and worked in regulatory affairs at Watson Pharmaceuticals prior to Teva's acquisition of Watson. Ms. DelGaudio will testify about the content and timing of Watson/Teva's application to make and sell generic Colcrys, including correspondence with FDA and timing of FDA approvals and actions.

11. Sanjay Dhandukia (fact witness identified with Amneal) Live

Mr. Dhandukia is Director of Strategic Portfolio Management at Amneal Pharmaceuticals and is responsible for coordinating all aspects of commercial launch of Amneal's drug products, including Amneal's launch of generic Colcrys in 2020. Mr. Dhandukia will testify about his experience at Amneal since August 2019 and the actual steps taken and timeline of Amneal's manufacturing of generic Colcrys from December 2019 to the launch of the product in May 2020.

12. Francis DiGiovanni (fact witness identified with Takeda) Live

Mr. DiGiovanni is a partner at the law firm Faegre Drinker Biddle & Reath LLP in Wilmington, Delaware. Mr. DiGiovanni represented Takeda in its injunction litigation against Mylan, following Mylan's surprise generic Colcrys launch. Mr. DiGiovanni submitted signed pleadings to the court on Takeda's behalf describing the motivation for and operation of the conspiracy.

13. Porter Fleming (fact witness identified with Takeda) Live

Mr. Fleming is a partner at the law firm Haug Partners in New York, NY. Mr. Fleming represented Takeda in its injunction litigation against Mylan, following Mylan's surprise generic Colcrys launch. Mr. DiGiovanni submitted signed pleadings to the court on Takeda's behalf explaining the operation of and motive for the conspiracy.

14. William Gazda (fact witness identified with Takeda) Live

Mr. Gazda has been the head of Takeda's Established Brands Portfolio since July 2019. Mr. Gazda also served as a 30(b)(6) corporate witness for Takeda in this case. Mr. Gazda will testify about the extent of different uses of Colcrys, Takeda's marketing of AG Colcrys through generic manufacturers, Takeda's approach to forecasting, Takeda's forecasting related to Colcrys, and the impacts of the launch of generic Colcrys by manufacturers in 2019 and 2020. Plaintiffs had planned to play Mr. Gazda's video to the jury, but because Takeda has indicated it will present him live, Plaintiffs will cross-examine Mr. Gazda in Defendants' case in chief.

15. Peter Gorevic (expert)

Dr. Gorevic is the Chief of the Division of Rheumatology at the Icahn School of Medicine at Mount Sinai School of Medicine in New York, and Emeritus Professor of Medicine and Pathology at the State University of New York at Stony Brook. He will testify about how colchicine is used in the context of gout and FMF, and opine on the evidence and substantive medical and technical issues implicated by Takeda's patents, including why and how those issues bear on noninfringement and invalidity.

16. Kapil Gupta (fact witness identified with Amneal) Live

Mr. Gupta has worked at Amneal Pharmaceuticals since 2012 and is Director of Business Development and Portfolio Strategy. Mr. Gupta will testify about his experience at Amneal running drug product launches and discussions of launches with executive leadership from 2015 to 2019, the time period relevant to Mr. Allen's expert opinion about earlier Amneal launch but for Defendants' anticompetitive conduct. Plaintiffs had planned to play Mr. Gupta's video to the jury, but because Amneal has indicated it will present him live, Plaintiffs will cross-examine Mr. Gupta in Defendants' case in chief.

17. Karen Keller (fact witness identified with Par) Live

Ms. Keller is a partner at the law firm Shaw Keller LLP in Wilmington, Delaware. Ms. Keller represented Par Pharmaceutical, Inc. when Par sought to intervene in Takeda's injunction litigation against Mylan, following Mylan's surprise generic Colcrys launch. Ms. Keller signed statements to the court on Par's behalf that describe the operation of and motive for the conspiracy.

18. George Kokkines (fact witness identified with Takeda) Video

Mr. Kokkines was Takeda's Vice President and Deputy General Counsel and lead inhouse settlement negotiator. Mr. Kokkines' testimony will focus on the negotiations and events leading to the at-issue agreements and related conspiracy.

19. Russel Lamb (expert)

Dr. Lamb has over 30 years of experience studying the economics of markets and prices. Dr. Lamb will testify regarding the expert opinions detailed in his reports in this case including opinions regarding the relevant market, Takeda's monopoly power, harm to competition, Plaintiffs' antitrust injury, whether the actions of Takeda, Par, Watson, and Amneal were consistent with their unilateral economic interests absent collusion, the absence of procompetitive justifications for the alleged misconduct, and the overcharge damages suffered by Plaintiffs.

20. Alpesh Patel (fact witness identified with Amneal) Video

Mr. Patel has worked at Amneal Pharmaceuticals since 2012 and is Senior Vice President of Global Regulatory Affairs and Head of Strategic International Expansion. Mr. Patel will testify about the content and timing of Amneal's drug application for generic Colcrys, including correspondence with FDA and timing of FDA approvals and actions.

21. Victoria Spataro (fact witness identified with Watson/Teva) Live

Ms. Spataro was Watson's lead settlement negotiator and the in-house counsel responsible for the Colcrys Patent Litigation and Watson's settlement; post-settlement, Ms. Spataro continued in her same inhouse counsel role after Teva completed its acquisition of Watson in August 2016. Ms. Spataro's testimony will focus on Watson's contemporaneous, nonprivileged statements about the weakness of Takeda's intellectual property, and the negotiations and events leading to the at-issue agreements and related conspiracy.

22. Lars Taavola (fact witness identified with Amneal) Live

Mr. Taavola was Amneal's Senior Patent Counsel and Head of Patent Litigation. Mr. Taavola supervised Amneal's attorneys working on the Colcrys patent litigation and participated in Amneal's settlement negotiations with Takeda. His testimony will focus on the Colcrys patent litigation, settlement negotiations, and at-issue settlements and related conspiracy.

23. Heather Takahashi (fact witness identified with Takeda) Video

Ms. Takahashi is a partner at the law firm Munger Tolles & Olson LLP in Los Angeles, California. Ms. Takahashi represented Takeda in Takeda's Hatch-Waxman lawsuits against Par, Watson, Amneal and subsequent "Third Wave" ANDA filers like Mylan and others. Ms. Takahashi's testimony will focus on the agreements that formed the conspiracy and Takeda's performance of its promises under the conspiracy and enforcement of the conspiracy.

24. Bernice Tao (expert)

Ms. Tao has 28 years of experience in pharmaceutical operations and supply chain management and currently offers development, regulatory, and strategic consulting services to the pharmaceutical industry as President and Senior Consultant of BT Regulatory Consulting Solutions. Ms. Tao will testify about the expert opinions she has formed in this case about the ability and timing of Amneal and Watson/Teva to gain regulatory approval of their generic Colcrys drug applications from FDA absent the challenged conduct and following a generic victory in the Colcrys patent litigation.

25. Jay Thomas (expert)

John R. Thomas has been a professor of law at Georgetown University in Washington D.C. since July 2002. Professor Thomas will give testimony to educate the jury about the complex Hatch-Waxman Act and corresponding regulatory regime that governs pharmaceutical drug applications and their approval. Professor Thomas will testify specifically about the expert opinions he has formed in this case about any patent barriers or marketing exclusivities that would have impacted the timing of generic ANDA approval, when those barriers and exclusivities would have expired or otherwise ended, as well as how the agreements between Defendants provided artificial exclusivities beyond those intended or provided for in the Hatch-Waxman Act.

26. Paul Tully (fact witness identified with Amneal) Video

Mr. Tully was a partner at the law firm McDonnel Boehnen Hulbert & Berghoff LLP, in Chicago, Illinois. Mr. Tully represented Amneal in the Colcrys patent litigation and served as its lead outside counsel. His testimony will focus on the Amneal's contemporaneous nonprivileged statements about the weakness of Takeda's intellectual property, settlement negotiations, and the at-issue agreements and related conspiracy.

27. Jeffrey Weinberger (fact witness identified with Takeda) Live

Mr. Weinberger was lead counsel for Takeda in the Colcrys patent litigation and was a partner at Munger Tolles & Olson in Los Angeles, California. His testimony will focus on settlement negotiations, the at-issue agreements, and the related conspiracy. Plaintiffs cannot serve a subpoena on Mr. Weinberger, but Takeda has indicated it may call him as a live witness. There is no deposition of Mr. Weinberger in this case. Because of his role in the alleged conspiracy in this

case, and because of his testimony's potential to shorten the presentation of Plaintiffs' case substantially, Plaintiffs have asked Takeda to make him available for Plaintiffs' case in chief.

28. Natalia Wojcik (fact witness identified with Watson/Teva) Live

Ms. Wojcik is Associate Director, Global New Product Introduction at Teva Pharmaceuticals and was previously supporting the Director of Project Management at Watson Pharmaceuticals before Teva's acquisition of Watson. Ms. Wojcik was responsible for coordinating all aspects of commercial launch of Teva's generic Colcrys in 2020 and will testify about her experience at Watson/Teva since 2015 and the actual steps taken and timeline of Teva's manufacturing of generic Colcrys up to the launch of the product in December 2020.

29. Matthew Woods (fact witness identified with Takeda) Video

Mr. Woods was Senior director of Takeda's gout franchise from April 2014 to December 2015, and was responsible for P&L, understanding the competitive landscape, scenario planning, and forecasting. Mr. Woods' testimony will focus on the relevant market, Takeda's market share, and settlement-related forecasting.

30. Amneal's keeper of records witness

Amneal's designated keeper of records witness will provide testimony laying a foundation for the admissibility of one exhibit.

31. Teva's and Watson's keeper of records witness(es)

Teva's and Watson's designated keeper of records witness(es) will provide testimony laying a foundation for the admissibility of certain exhibits.

* * *

Plaintiffs reserve the right to call witnesses for rebuttal purposes based on Defendants' case.

V. <u>PLAINTIFFS' EXHIBITS</u>

A list of exhibits and descriptions thereof is appended hereto as Exhibit A.

VI. <u>DEPOSITION TESTIMONY</u>

Highlighted deposition testimony is appended hereto as Exhibits B-G. The pages and line numbers of testimony are:

Lawrence Brown

l	8:2-8:10	91:15-91:21	112:13-113:14	132:15-133:3	193:19-193:22
	8:16-8:19	91:23-92:6	113:23-114:1	142:11-142:21	196:20-196:25
	12:10-13:5	92:9-92:18	114:4-114:7	142:25-143:3	197:25-198:4
	23:6-23:23	92:22-93:7	114:20-114:23	143:5-143:13	201:2-201:6
	23:25-24:4	93:9-93:12	115:1-115:1	143:17-143:21	201:14-201:18
	25:4-25:24	95:2-95:7	115:6-115:10	144:6-144:10	201:20-201:23
	54:22-54:25	95:19-95:22	116:13-116:15	144:12-144:15	201:25-201:25
	55:4-55:9	95:25-96:2	116:22-116:22	149:10-149:13	205:21-206:1
	56:4-56:19	96:4-96:17	116:24-117:24	149:17-149:19	206:11-206:12
	76:2-76:10	96:20-96:20	119:21-121:10	150:19-151:15	206:14-206:21
	76:18-76:24	97:8-97:17	121:18-121:18	151:19-151:21	206:24-206:24
	77:1-77:7	98:3-98:6	122:18-122:20	171:22-172:15	210:2-210:6
	77:15-78:9	98:9-98:16	123:1-123:1	173:14-173:21	210:9-210:12
	79:8-79:17	104:8-104:11	125:4-125:13	176:24-177:12	230:14-230:24
	85:17-85:19	104:14-104:19	125:21-125:25	177:14-177:17	247:25-248:7
	85:23-86:1	104:21-105:8	126:2-126:25	191:11-191:22	250:14-250:17
	86:3-86:7	105:19-105:21	127:7-128:7	191:24-191:24	251:5-251:9
	87:17-88:15	105:23-106:1	130:2-130:3	192:22-192:25	251:17-252:6
	90:4-91:13	110:13-111:3	130:8-130:10	193:2-193:3	

[SPACE INTENTIONALLY LEFT BLANK]

George Kokkines

_				
9:19-10:4	99:22-100:8	173:17-173:17	209:2-209:9	260:21-260:21
10:12-10:16	100:10-100:11	179:7-179:21	209:12-209:12	260:23-260:23
12:14-12:20	100:13-100:15	181:12-181:24	209:18-211:12	261:3-261:6
13:3-13:6	100:24-101:1	185:11-185:24	211:20-212:16	261:14-262:4
13:15-13:21	101:3-101:6	186:2-186:2	212:19-212:21	263:20-264:8
31:21-32:1	101:8-101:11	186:4-186:10	212:23-213:23	264:10-264:13
33:3-33:23	102:15-103:4	186:15-186:17	216:6-216:10	264:15-264:24
34:12-34:17	103:7-103:8	188:11-188:15	216:15-217:8	266:13-267:11
34:24-35:3	103:14-103:15	189:7-190:16	217:10-218:5	267:13-267:14
36:18-37:11	106:2-106:11	191:6-191:18	218:7-218:7	267:16-268:6
37:17-37:17	107:20-108:21	191:20-192:9	218:9-218:11	268:8-268:9
37:20-37:22	109:19-110:15	192:11-192:11	218:13-218:17	268:11-268:16
40:16-40:19	110:17-111:4	192:13-192:14	219:10-219:15	269:3-272:8
41:3-41:6	111:6-111:8	192:16-192:16	220:4-223:15	274:1-275:21
43:6-43:16	111:10-111:11	192:18-192:19	223:21-224:1	275:23-276:1
53:16-53:19	113:3-113:4	192:21-192:21	224:4-224:5	276:3-276:16
54:22-55:12	113:6-113:7	192:23-192:24	224:7-224:24	277:15-277:23
56:1-56:16	113:19-113:22	193:2-193:2	225:3-225:4	278:1-278:1
62:14-62:22	113:24-114:5	193:22-193:24	225:6-225:7	278:3-278:5
63:24-64:1	114:13-114:23	194:2-194:13	225:13-226:13	278:13-278:23
64:6-64:6	115:1-115:1	194:20-194:21	227:15-228:6	279:10-280:22
64:8-65:7	115:3-115:6	194:23-195:2	240:13-240:22	281:5-281:8
68:13-68:14	115:9-115:21	195:4-195:5	244:22-244:24	295:3-295:7
70:1-70:6	126:19-126:19	195:7-195:11	245:10-245:24	295:11-295:23
75:21-76:2	126:23-127:2	195:13-195:14	246:2-246:19	296:19-297:8
78:2-78:21	127:6-128:19	195:16-195:17	246:22-246:22	298:9-298:20
78:24-79:2	128:22-129:5	195:19-195:19	246:24-248:2	298:22-299:2
79:7-79:8	129:7-129:7	196:11-197:2	248:7-248:11	299:4-299:9
79:10-79:11	129:9-129:13	197:11-198:4	248:13-248:15	299:12-299:13
79:13-79:16	129:15-129:21	198:7-198:10	248:17-248:18	299:15-299:17
91:16-91:16	129:23-130:2	198:13-198:17	248:20-249:8	299:20-299:20
92:10-93:4	130:4-130:5	199:17-200:22	249:13-249:17	299:22-299:24
95:9-95:14	130:7-130:14	200:24-201:2	249:19-249:20	300:2-300:4
95:21-95:23	134:2-134:4	201:4-201:6	250:4-250:24	300:6-300:17
96:1-96:2	134:8-134:9	201:11-201:15	251:2-251:2	300:24-301:1
98:2-98:12	134:15-135:7	201:17-201:22	251:4-252:2	301:4-301:21
98:21-98:23	135:12-136:3	202:7-202:18	252:5-252:6	301:24-302:7
99:1-99:7	136:5-136:7	203:15-203:20	259:23-259:24	
99:9-99:9	136:9-136:14	208:1-208:6	260:2-260:6	334:24-334:24
99:11-99:13	170:11-172:10	208:13-208:17	260:8-260:14	
99:19-99:20	172:15-173:2	208:19-208:23	260:16-260:19	

Alpesh Patel	8:24-8:25	27:2-27:3	49:24-49:25	64:15-64:21	80:23-80:24
	9:9-9:21	27:6-27:8	50:2-50:7	66:5-68:16	81:18-81:22
	11:4-11:11	28:11-28:15	55:7-55:10	69:12-69:15	82:2-82:11
	12:12-12:14	28:17-29:13	57:21-57:24	69:17-69:25	82:13-82:17
	23:2-23:9	29:15-29:19	58:17-58:25	70:2-70:2	82:21-82:24
	23:11-23:16	29:21-29:24	60:19-60:21	70:4-70:6	83:9-83:11
	23:24-23:25	31:4-31:11	60:24-61:6	70:9-70:16	83:19-83:25
	25:6-25:25	31:13-31:15	61:8-63:2	72:24-72:25	84:2-84:3
	26:17-26:20	48:15-48:21	63:14-63:18	73:2-73:8	84:15-84:22
	26:23-26:25	49:7-49:10	63:21-64:13	73:10-73:19	
Heather					
Takahashi	6:12-7:3	32:17-35:10	77:1-78:13	86:16-87:7	98:12-100:1
	10:17-10:22	35:12-35:20	78:15-78:24	87:9-87:18	100:3-100:5
	14:14-14:16	36:4-36:12	79:1-79:13	87:20-87:23	103:3-104:22
	24:2-26:14	36:14-36:15	79:25-80:7	93:20-94:6	105:9-108:10
	26:16-26:18	71:21-72:4	80:24-83:13	95:3-98:10	
					1
Paul Tully	6:16-7:15	35:11-35:20	60:10-60:13	75:13-75:16	86:21-86:22
	9:14-9:16	36:11-36:16	60:16-60:21	75:19-75:22	87:5-88:5
	9:18-10:4	36:19-36:24	60:24-60:24	75:25-76:1	88:8-88:13
	13:20-13:22	37:14-37:19	61:24-63:3	77:10-78:11	89:18-89:20
	18:17-19:9	50:9-51:17	64:5-65:2	78:13-78:23	89:24-90:3
	19:11-19:11	51:19-51:21	65:24-66:8	79:1-79:2	90:6-90:13
	24:20-24:23	51:24-52:6	66:12-66:17	79:23-80:11	90:16-90:19
	25:2-25:12	52:10-52:18	66:19-67:8	80:13-80:24	90:22-91:2
	25:15-25:16	52:21-52:25	67:11-67:21	81:22-81:24	91:5-91:13
	25:18-25:24	53:3-53:7	68:4-68:5	82:2-82:6	91:15-91:16
	26:2-26:6	53:10-53:11	69:23-70:1	82:9-82:9	96:20-97:15
	26:9-26:19	54:6-54:12	70:3-70:10	84:20-84:25	97:18-98:7
	27:20-28:3	54:25-55:7	72:2-72:5	85:17-85:19	98:9-98:23
	30:4-30:5	55:15-56:4	72:9-72:9	85:21-85:24	99:1-99:7
	30:11-30:12	56:8-56:20	74:3-74:6	86:1-86:3	99:14-100:5
	34:22-34:24	56:23-57:3	74:10-74:16	86:5-86:9	100:10-100:13
	35:1-35:8	57:6-57:20	75:7-75:10	86:14-86:18	100:16-100:17

Matthew Woods

9:12-9:14	80:20-80:23	168:14-168:23	179:18-179:20	207:5-207:25
12:6-12:11	146:1-146:9	172:13-173:10	180:6-180:19	215:12-215:16
22:2-22:8	158:17-160:2	173:23-173:25	181:6-181:23	215:23-216:1
25:7-26:9	166:1-166:17	174:21-177:4	183:25-185:25	216:10-216:25
79:18-79:25	166:20-167:6	178:18-179:2	203:12-204:1	
80:13-80:17	167:8-168:1	179:12-179:15	205:12-206:16	

VII. <u>CONTESTED EXHIBITS</u>

In accordance with this Court's Scheduling Order, ECF No. 904 ¶ 13, Plaintiffs will file a list of contested exhibits, and provide two courtesy copies to Chambers, on August 18, 2023.

VIII. STIPULATIONS OF COUNSEL

None.

IX. SPECIAL COMMENTS REGARDING LEGAL ISSUES

A. Expected Motions in Limine

Plaintiffs expect to file motions in limine:

- 1. To preclude the testimony of Magistrate Judge Thynge in addition to reference to or argument about (a) the involvement of Magistrate Judge Thynge, and (b) the submission of settlement agreements to the FTC or DOJ.
- 2. To exclude reports by third-party firm IPD Analytics about the patents at issue.
- 3. To preclude the use of assertedly privileged information at trial on subject matters Defendants blocked during discovery.
- 4. To preclude undisclosed expert testimony including through purported fact witness Dr. Matthew Davis.

B. Defendants' Late Disclosure of Magistrate Judge Thynge as a Witness

Defendants suddenly amended their Rule 26(a)(1) disclosures on the eve of trial to add Magistrate Judge Thynge as an individual "likely to have discoverable information that [Defendants] may use to support [their] claims and/or defenses." Thereafter they indicated they were calling her as a witness. "It has long been recognized that attempts to probe the thought and decision making processes of judges and administrators [is] generally improper" because it poses a "substantial threat" to the judicial process. *Grant v. Shalala*, 989 F.2d 1332, 1344-45 (3d Cir. 1993). Even for fact testimony, only if the judge "is [] the only possible source of testimony" can judicial testimony even be considered. *See Ciarlone v. City of Reading*, 263 F.R.D. 198, 205 (E.D. Pa. 2009) (citing three-prong test in *United States v. Frankenthal*, 582 F.2d 1102 (7th Cir. 1978)), *aff'd*, 489 Fed. Appx. 567, 570 (3d Cir. 2012) ("Calling a judge to give testimony in any proceeding

is a very delicate matter because factual testimony from a judge unduly can affect a jury.") (citations and quotations omitted). See In re Linerboard Antitrust Litig., No. MDL 1261, 2008 WL 4461914, at *5 (E.D. Pa. Oct. 3, 2008) (disapproving of calling Magistrate Judge Rueter to give fact testimony about mediations in antitrust litigation, despite their relevance to dispute arising from settlement).

Moreover, the last-minute addition of Judge Thynge is untimely and compounds the unfairness to Plaintiffs to be addressed separately in Plaintiffs' motion *in limine*. As will be explained therein, any reference to Judge Thynge's role in the formation of the agreements in this case would have no purpose other than to prejudice Plaintiffs by causing the jury to erroneously infer that a judicial officer placed her imprimatur on those settlements as compliant with the antitrust laws when she did nothing of the sort. Controlling Third Circuit law prevents defendants from implying that her signature or involvement is relevant to their antitrust liability. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 262-66 (3d Cir. 2017). Instead, she was limited to the role of mediator, and permitting her to testify about that mediation would be inequitable given that Watson and Amneal earlier successfully blocked discovery about their mediation positions. ECF No. 412.

Moreover, Rule 26(e) requires that supplementation be achieved "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Defendants do not, and cannot, explain what new information they recently learned to suddenly cause them to add Judge Thynge to their disclosures.

Plaintiffs relied on Defendants' initial disclosures throughout discovery and it obviously would be inequitable to permit the Defendants to ambush Plaintiffs with a belatedly designated witness. *Pac-West Distrib. NV LLC v. Afab Indus. Servs., Inc.*, 2023 U.S. Dist. LEXIS 101963 (E.D. Pa. June 12, 2023) (precluding defendants from calling witnesses it did not disclose until the eve of trial); *Amidon v. Goodyear Tire & Rubber Co.*, 2021 U.S. Dist. LEXIS 256034, at *1-4 (M.D. Pa. Sep. 2, 2021) (same); *Schmidt v. Mars, Inc.*, 2012 U.S. Dist. LEXIS 50095, at *2-6 (D.N.J. Apr. 10, 2012) (same); *Roberts v. United States*, 2012 U.S. Dist. LEXIS 86762, at *17-18 (D.N.J. June 22, 2012) (same).

C. <u>Defendants Should Be Prohibited from Suggesting Incorrect Law About Conspiracy</u>

It is improper for a party to suggest to the jury what the law is, particularly when the suggestion is inaccurate. The Court should prohibit Defendants from doing so.

1. Conspiracy Does Not Require a "Smoke-Filled Room"

Defendants have argued that there was no concert of action because the challenged agreements were not executed simultaneously, without a simultaneous meeting or communication involving all of them together planning out the conspiracy, or without the full details of the conspiracy known to every conspirator. *E.g.*, ECF No. 206, March 10, 2022 Hr'g Tr. at 60:10-13 (defense counsel referring to lack of "actual evidence that all the participants sat down in a room and decided how things would be ordered."); ECF No. 744-1, Takeda's Mem. of Law. In Supp. of Mot. for Summ. J. at 10 ("Plaintiff has no evidence of any agreement among all four Defendants."); *id.* at 14-16 (incorrectly claiming that the generic conspirators did not know or have expectations about the terms of one another's agreements). But controlling law is clear that a conspiracy can be formed at different times, and each conspirator need not know all its details. *See Interstate Circuit*

v. United States, 306 U.S. 208, 227 (1939) ("It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators . . . [a]cceptance by competitors without previous agreement of an invitation to participate in a plan . . . is sufficient to establish an unlawful conspiracy under the Sherman Act."); United States v. Katzin, 782 F.2d 1029 (3d Cir. 1986) (conspiracy exists even if "there has been no direct contact whatsoever amongst some of its links.") (citation omitted); United States v. Berkery, 889 F.2d 1281, 1284 (3d Cir. 1989) (approving of a jury charge that "You can become a member of a conspiracy without knowing all the details of the unlawful scheme or even without knowing the names and identities of all the other alleged conspirators."); United States v. Adams, No. 15-0580, 2019 U.S. Dist. LEXIS 9558, at *15 (E.D. Pa. Jan. 16, 2019) ("no requirement exists where all conspirators must know and agree to all details of the conspiracy or know what others in the conspiracy are doing.").

Plaintiffs' proposed Jury Instruction No. 27 deals with this issue. It cites ABA MODEL CIVIL ANTITRUST INSTRS., Ch. 2, Instr. A-1 (modified as proposed in ABA notes). Plaintiffs respectfully submit that the Defendants should not be permitted to argue that a finding of concerted action requires simultaneous agreement and knowledge about all the conspiracy's details.

2. Using an Agent to Effectuate a Conspiracy, Such as Outside Counsel, Does Not Immunize the Principal

Defendants have likewise incorrectly argued that they did not conspire because certain communications of offers, acceptances, agreements, and recruitment efforts were "only" made by or to a Defendant's outside counsel on an "outside counsel only" basis. See ECF No. 737-1, Watson, Teva and Amneal's Mem. of Law in Supp. of Mot. for Summ. J. at n.5 (arguing a lack of conspiracy based on the assertion that only the conspirators' outside counsel were aware of the specific conspiracy terms); ECF No. 801 at 8-9, Defs.' Opp'n to Pls.' Mot. for Partial Summ. J., (same). But controlling law is clear that an agent with apparent authority can bind the principal to a conspiracy, and a lawyer's knowledge is imputed to his or her client. See Irwin v. Dep't of Veterans Affs., 498 U.S. 89, 92 (1990) ("Under our system of representative litigation, 'each party is deemed bound by the acts of his lawyer-agent and is considered to have notice of all facts, notice of which can be charged upon the attorney.") (quoting Link v. Wabash R. Co., 370 U.S. 626, 634 (1962); Alvord-Polk, Inc. v. F. Schumacher & Co., 37 F.3d 996, 1009 (3d Cir. 1994) ("Applying that general principle [that apparent authority results in liability on a principal's part for an agent's torts] to the antitrust area leads us to conclude that a principal will be liable for an antitrust violation if an agent acting with apparent authority violates the antitrust laws, as one did in *Hydrolevel* by conspiring with another person.") (citing Am. Soc'y of Mech. Eng'rs, Inc. v. Hydrolevel Corp., 456 U.S. 556, (1982)); In re Kensington Int'l Ltd., 368 F.3d 289, 315 (3d Cir. 2004) ("Aside from the fact that the attorney is only one step removed from the client, the attorney and client have an agency relationship and therefore any facts known by the attorney may generally be imputed to the client."). See also Higgins v. Shenango Pottery Co., 256 F.2d 504, 509 (3d Cir. 1958) ("it is a rule of agency that the knowledge of the agent is imputed to the principal in connection with any transaction conducted by the agent in behalf of his principal"), cited in In re Color Tile Inc., 475 F.3d 508, 513 (3d Cir. 2007).

Plaintiffs' proposed Jury Instruction No. 29 deals with this issue. Defendants should not be permitted to argue that their conduct was insulated from liability because it was laundered through counsel.

D. <u>Defendants Should Be Precluded from Offering Evidence from Unrelated and</u> Irrelevant Antitrust Cases

The Court should preclude Defendants from introducing evidence from unrelated cases. For example, Defendants' exhibit list contains trial transcripts from the Opana reverse payment litigation, a pay-for-delay case under *Actavis*. That case involved the opioid medication, "Opana." That case involved an entirely different set of facts and evidence. Thus, testimony, evidence, patents, or other argument relating to Opana (or other litigation not directly related to this case) is irrelevant and carries a high risk of jury confusion and undue prejudice.

E. <u>Defendants Should Be Prevented from Suggesting "Pass-On" of Overcharges</u>

Defendants may try to argue or imply that Plaintiffs "passed-on" overcharges to their downstream customers. This is impermissible under controlling law. A direct purchaser is "injured within the meaning of § 4 [of the Clayton Act] by the full amount of the overcharge paid by it and . . . the antitrust defendant is not permitted to introduce evidence that indirect purchasers were in fact injured by the illegal overcharge." Illinois Brick Co. v. Illinois, 431 U.S. 720, 724-725 (1977) (emphasis added). See also Hanover Shoe v. United Shoe Machinery Corp., 392 U.S. 481, 494 (1968) (same).

Plaintiffs' proposed Jury Instruction No. 55 deals with this issue. Defendants should not be permitted to argue or imply that Plaintiffs were less injured or uninjured because of any purported "pass on" to their own customers.

F. <u>Defendants May Impermissibly Refer to Treble Damages</u>

Defendants may try to encourage a lower award of damages in this case by suggesting to the jury that damages will already be automatically trebled. Any such suggestion should be prohibited, as it would be irrelevant and prejudicial. Treble damages are mandated by the Clayton Act "to encourage private plaintiffs to bring suit," and "[a]ny ultimate recovery totaling less than three times proven damages would weaken the statutory incentive through judicial construction." Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp., 995 F.2d 425, 448 (3d Cir. 1993) (quotation and citation omitted). Plaintiff's entitlement to treble damages or attorneys' fees is inadmissible in a jury trial of an antitrust claim. See C. Albert Sauter Co., Inc. v. Richard S. Sauter Co., Inc., 368 F. Supp. 501, 517-18 (E.D. Pa. 1973) (recognizing that "[i]t is the practice in this district to refrain from advising the jury about the trebling of damages" and concluding that the jury in antitrust cases should not be advised of potential for trebling of award). Cf. United States v. Bombardier Transp. (Holdings) USA, Inc., 656 F. Supp. 2d 540, 547 (W.D. Pa. 2009) (recognizing the "great weight of authority in a variety of other contexts establishing a general rule that it is error to instruct a jury as to treble damages, attorneys fees, or other court-determined awards that might corrupt the jury's damage determination").

G. Plaintiffs' Claims for Relief

By order dated March 30, 2022 (ECF No. 207), this Court left intact the following Claims for Relief:

- Count I: Single Conspiracy Among All Defendants in Restraint of Trade (Against All Defendants)
- Count V: Monopolization (Against Takeda Only)
- Count VI: Conspiracy to Monopolize (Against All Defendants)

To streamline their case, Plaintiffs will pursue only Counts I and V. Plaintiffs hereby withdraw Count VI, with prejudice.

H. <u>Time Allocated to the Parties</u>

Plaintiffs and Defendants have attempted to predict the time each of their respective direct and cross examinations of each witnesses will consume, to fairly allocate the 14 trial days. This is presented below.

I. Scope of Plaintiffs' Expert Testimony

During Plaintiffs' case in chief, Plaintiffs intend to have their experts rebut the disclosed expert opinions of Defendants' opposing experts, which will reduce or eliminate the need to recall Plaintiffs' experts for rebuttal after Defendants' case in chief. In an antitrust case, there are shifting burdens, and so Plaintiffs are ordinarily permitted rebuttal.

J. Jury Binders

To aid the jury in considering the evidence, Plaintiffs propose that the jurors' exhibit binders be indexed, sorted by witness and date, and highlighted in different colors by each side. An orderly presentation will facilitate the jury's understanding and recall of the evidence.

X. THE PARTIES' RESPONSES TO THE COURT'S AUGUST 9, 2023 ORDER (ECF NO. 983)

1. The parties agree that there should be a unanimous verdict. The parties disagree with respect to the total number of jurors.

<u>Plaintiffs' position:</u> Plaintiffs agree to a jury of ten.

<u>Defendants' position</u>: Given the length of the trial and potential for trial days to extend beyond seven hours per day, Defendants request that the Court empanel a jury of twelve persons to ensure the return of a unanimous verdict of at least six jurors. Although the Court has scheduled fourteen trial days, the trial is likely to span the entire month September, after accounting for the three dates on which trial will not be held (September 22, 25-26) and including the possibility that there will be no trial on Fridays. Recent experience has shown that the number and length of trial days increases the risk that jurors will drop out before the end of trial. Defendants respectfully submit that there is minimal burden to the Court and parties in empaneling two additional jurors beyond the ten the Court already intends to impanel, and any such burden is outweighed by the need to ensure the return of a unanimous verdict of at least six jurors at the end of this month-long trial.

2. The parties disagree as to length of opening statements per side.

<u>Plaintiffs' position</u>: Plaintiffs agree to opening statements limited to one hour total per side.

<u>Defendants Amneal and Teva/Watson's position</u>: In light of the complexity of the case and the fact that each of the four individual Defendants (Takeda, Amneal, Teva, and Watson) have unique arguments and defenses applicable to each of them, Amneal, Teva, and Watson request that the Court allocate equivalent time for opening statements on a per-Defendant basis (but treating Teva and Watson collectively as a single Defendant). Amneal, Teva, and Watson request forty-five minutes for Amneal and forty-five minutes for Teva/Watson, which would allow their counsel to give an opening statement on behalf of both of them of 90 minutes.

Good cause exists for modification of both the time and "per side" allocations set forth in Rule X.I of Your Honor's Policies and Procedures. As explained in Section VII.A of the Defendants' Joint Pre-Trial Memo, each Defendant must address unique claims, issues, and defenses. For example, Amneal has defenses related to the fact that none of the settlement terms Plaintiffs allege had an anticompetitive effect exist in Amneal's term sheet or settlement agreement and, specifically, there is no evidence the 135-Day Term was ever known to Amneal. And Teva/Watson have a unique causation defense related to the fact that Teva's policies would have prevented Teva from launching its generic Colcrys product until at least January 2020, if not later, even under a scenario where patent or regulatory barriers to Teva's launch had not existed. In order to allow each Defendant to present its defenses fully and adequately to the jury, counsel for Amneal and Teva/Watson should be permitted to address the jury through an opening statement separate from Takeda's opening.

<u>Defendant Takeda's position:</u> Takeda respectfully requests no less than 45 minutes to present its opening statement in this complex case. Takeda takes no position on the request by counsel for Amneal, Teva and Watson for greater time, and has no objection to Plaintiffs receiving equal time to that afforded Defendants collectively.

3. All parties will work within an allocation of 14 trial days, inclusive of openings and closings (but presumably not inclusive of jury deliberations). The parties will be responsible for keeping track of time per side at trial and agree to reconcile their time daily. To the extent any disagreements arise, the parties will raise with the Court promptly. The parties' best estimates of the time required for each witness in direct and cross is as follows. The parties' estimates are subject to change based on the witnesses that are called, as well as rulings on forthcoming motions *in limine*.

PLAINTIFF CASE					
Name	Ps' Direct/Cross	Ds' Cross/Redirect	Witness Total		
Allen (E)	1:10	1:00	2:10		
Belvis (E)	2:30	2:30	5:00		
Bourke	0:30	1:00	1:30		
Bover	0:10	0:30	0:40		
Brown (D)	0:39	0:00	0:39		
Calabro	0:20	0:30	0:50		

C 11:	1.00	0.20	1.20			
Campanelli	1:00	0:30	1:30			
Cappel	1:35	1:45	3:20			
Ciarico	0:20	0:45	1:05			
DelGaudio	0:45	0:30	1:15			
Dhandhukia	0:20	0:30	0:50			
DiGiovanni	0:30	0:30	1:00			
Doc custodian Amneal	0:05	0:00	0:05			
Doc custodian Watson	0:20	0:00	0:20			
Fleming	0:30	0:30	1:00			
Gorevic (E)	2:30	1:20	3:50			
Keller	0:40	0:30	1:10			
Kokkines (D)	1:39	0:55	2:34			
Lamb (E)	2:00	3:30	5:30			
A. Patel (D)	0:22	0:00	0:22			
Spataro	1:30	2:00	3:30			
Taavola	1:35	2:00	3:35			
Takahashi (D)	0:35	0:05	0:40			
Tao (E)	1:10	0:30	1:40			
Thomas (E)	1:40	0:30	2:10			
Tully (D)	0:44	0:00	0:44			
Wojcik	0:20	0:30	0:50			
Woods (D)	0:35	0:00	0:35			
TOTAL P CASE	26:04	22:20	48:24			
DEFENSE CASE						
	DEFENSI	E CASE				
Name	Defension Defens	Ps' Cross/Redirect	Witness Total			
Name Alverson (MC) (D)			Witness Total 0:20			
	Ds' Direct/Cross	Ps' Cross/Redirect				
Alverson (MC) (D)	Ds' Direct/Cross 0:15	Ps' Cross/Redirect 0:05	0:20			
Alverson (MC) (D) Baker (E)	Ds' Direct/Cross 0:15 2:00	Ps' Cross/Redirect 0:05 1:00	0:20 3:00			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30	Ps' Cross/Redirect 0:05 1:00 0:15	0:20 3:00 0:45			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05	Ps' Cross/Redirect 0:05 1:00 0:15 0:20	0:20 3:00 0:45 0:25			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05	0:20 3:00 0:45 0:25 0:13			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00	0:20 3:00 0:45 0:25 0:13 3:00			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40	0:20 3:00 0:45 0:25 0:13 3:00 1:55			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC) Einhorn (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC) Einhorn (MC) (D) Gazda	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davies Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davies Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D) Igel (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45 0:05 0:25	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20 0:05 0:05	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05 0:10 0:30			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davies Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D) Igel (MC) (D) Jena (E)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45 0:05 0:25 2:00	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20 0:05 0:30 0:05 0:30	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05 0:10 0:30 2:30			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davies Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D) Igel (MC) (D) Jena (E) Kipp (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45 0:45 0:05 0:25 2:00 0:11	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20 0:05 0:30 0:05 0:30 0:05	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05 0:10 0:30 2:30 0:16			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davis Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D) Igel (MC) (D) Jena (E) Kipp (MC) (D) Lassman (E)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45 0:45 0:05 0:25 2:00 0:11 1:10	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20 0:05 0:30 0:05 0:30 0:05 0:30 0:40	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05 0:10 0:30 2:30 0:16 1:50			
Alverson (MC) (D) Baker (E) Brown (MC) Buonaiuto (MC) (D) Coppola (MC) (D) Cremieux (E) Davies (E) Davies Doghramji (E) (MC) Einhorn (MC) (D) Gazda Geilen (MC) (D) Groff Gupta Hawkey (MC) (D) Igel (MC) (D) Jena (E) Kipp (MC) (D)	Ds' Direct/Cross 0:15 2:00 0:30 0:05 0:08 2:00 1:15 1:30 1:00 0:12 1:00 0:10 0:45 0:45 0:45 0:05 0:25 2:00 0:11	Ps' Cross/Redirect 0:05 1:00 0:15 0:20 0:05 1:00 0:40 1:00 0:45 0:05 0:45 0:05 0:30 0:20 0:05 0:30 0:05 0:30 0:05	0:20 3:00 0:45 0:25 0:13 3:00 1:55 2:30 1:45 0:17 1:45 0:15 1:15 1:05 0:10 0:30 2:30 0:16			

Schoen (MC) (D)	0:06	0:05	0:11
Singer (E)	2:30	1:00	3:30
Strombom (E)	1:55	0:30	2:25
Thynge	1:30	0:30	2:00
Wagner (E)	0:45	1:00	1:45
Weinberger	2:00	1:00	3:00
TOTAL D CASE	24:34	12:35	37:09

(E) = expert

(MC) = defendants "may" call

(D) = by deposition

- 4. All parties agree to share 50/50 in the costs of juror lunches (and dinners if warranted during deliberations).
- 5. For logistics, Plaintiffs designate Raymond Barto (Faruqi & Faruqi LLP) and Defendants designate James Hileman (Kirkland & Ellis, for Amneal and Teva/Watson) and Vincent Papa (Morgan Lewis, for Takeda). Given that Defendants are represented by counsel from two separate law firms, Defendants respectfully request that a representative from each firm be authorized to communicate with Chambers on logistical matters.

Dated: August 15, 2023 Respectfully submitted,

VALUE DRUG COMPANY

By: <u>/s/ Dan Litvin</u>
One of Its Attorneys

Bruce E. Gerstein
Dan Litvin
Deborah A. Elman (Pa. I.D. 87503)
David B. Rochelson
GARWIN GERSTEIN & FISHER LLP
88 Pine Street, 10th Floor
New York, NY 10005
(212) 398-0055
bgerstein@garwingerstein.com
dlitvin@garwingerstein.com
delman@garwingerstein.com
drochelson@garwingerstein.com

David F. Sorensen (Pa. I.D. 57766) Caitlin G. Coslett (Pa. I.D. 306915) BERGER MONTAGUE PC 1818 Market Street, Suite 3600 Philadelphia, PA 19103 (215) 875-3000 dsorensen@bm.net ccoslett@bm.net Peter Kohn (Pa. I.D. 65454) Joseph Lukens (Pa. I.D. 67405) FARUQI & FARUQI LLP 1617 JFK Blvd, Suite 1550 Philadelphia, PA 19103 (215) 277-5770 pkohn@faruqilaw.com jlukens@faruqilaw.com

Bradley J. Demuth FARUQI & FARUQI LLP 685 Third Avenue New York, NY 10017 (212) 983-9330 bdemuth@faruqilaw.com

Stuart E. Des Roches Andrew W. Kelly **ODOM & DES ROCHES LLC** 650 Poydras Street, Suite 2020 New Orleans, LA 70130 Susan Segura
David C. Raphael
Erin R. Leger
SMITH SEGURA RAPHAEL
LEGER LLP
221 Ansley Blvd.
Alexandria, LA 71303
(318) 445-4480
ssegura@ssrllp.com
draphael@ssrllp.com
eleger@ssrllp.com

(504) 522-0077 stuart@odrlaw.com akelly@odrlaw.com

Russell Chorush
Christopher M. First
William B. Collier, Jr.
HEIM PAYNE & CHORUSH LLP
1111 Bagby Street, Suite 2100
Houston, TX 77002
(713) 221-2000
rchorush@hpcllp.com
cfirst@hpcllp.com
wcollier@hpcllp.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2023, I served the foregoing via ECF on all Defendants.

Dated: August 15, 2023

/s/ Dan Litvin
Dan Litvin